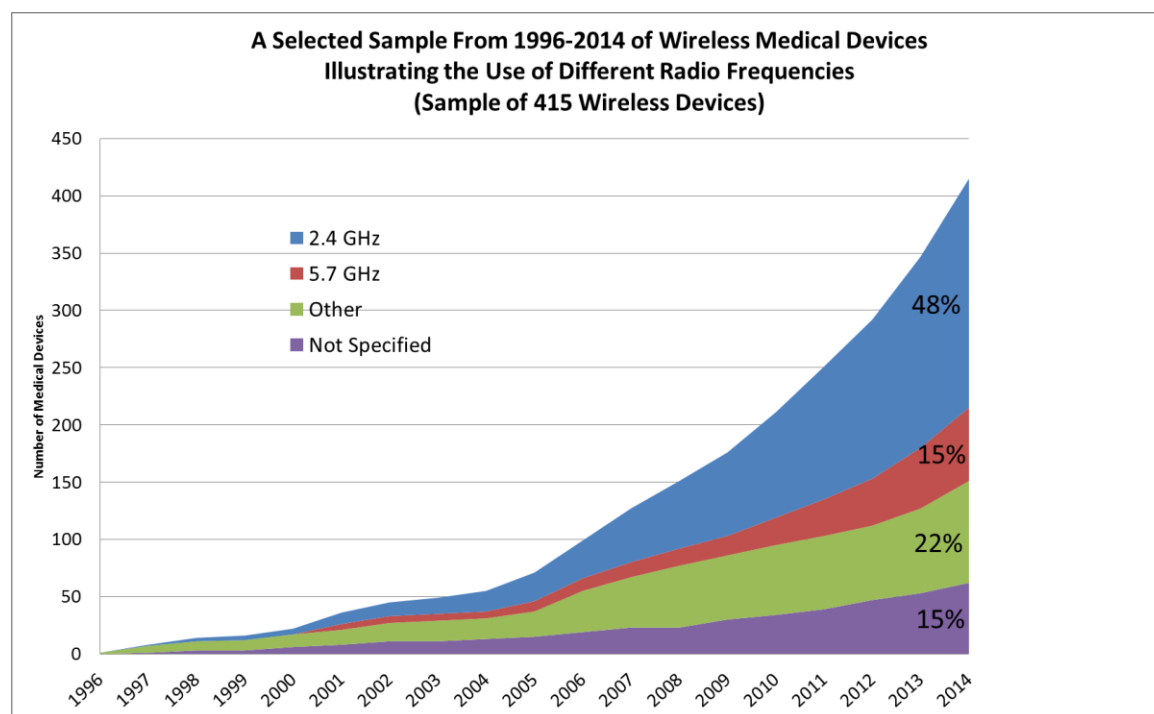


## Wireless Medical Devices: Some trends, challenges, and opportunities

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Abstract: Wireless technology has been incorporated into certain medical devices for many years. For example, wireless medical telemetry was modeled on the system used for astronauts and has provided safe and effective care for cardiac patient care for many years. In recent years the trend to integrate wireless technology has been on the rise as seen in a selected sample of over 400 wireless medical devices between 1996 and 2014 illustrated below.



This information also reveals that in recent years a large portion of the devices use wireless technology operating in the Industrial, Scientific, and Medical (ISM) band at 2.4 to 2.4835 GHz. Most of these devices use common wireless technology such as IEEE 802.11 “Wi-Fi”, Bluetooth, and ZigBee. These common wireless technologies utilize bands that are shared among many other products such as personal computers and smart phones. The medical device functions of the devices that integrate wireless technology span a wide variety of medical areas and functions including: vital signs monitoring, drug and insulin pump, pulse oximetry, implanted cardiac pacemakers, implanted cardioverter defibrillation, implanted (e.g., Deep Brain Stimulation) and body worn nerve stimulation, blood glucose monitoring, radiological imaging systems (including image transmissions), surgical imaging, nurse call systems, foot switch remote controls, and several others.

This rise in the use of wireless technology in medical devices helped spur the development of the *Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff*

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077210.htm>

This guidance is intended to help medical device designers, manufacturers, and regulators to better understand areas to consider in developing and implementing wireless medical devices and systems. These considerations include the selection of appropriate wireless technology that will enable the medical device to coexist with other wireless products and still be able to perform its intended function safely and effectively.

Currently, there are few references and no consensus standards available focused on wireless medical device coexistence. To help address this area CDRH is engaged in efforts by the American National Standards Institute (ANSI) certified standards organizations (ANSI certified C63.27 Wireless Technology Coexistence, Association for the Advancement of Medical Instrumentation (AAMI) standard committee work group SM/WG-06 on Wireless Medical Device Coexistence) to assess needs and challenges for coexistence and create a test method standard and technical information to address these issues. The AAMI group is developing a technical information report to provide understanding and risk management information for the unique issues associated with medical devices. This is part of a larger effort by AAMI and supported by FDA to provide information and resources to advance medical device systems.

Medical device manufacturers, regulators, healthcare organizations, and users have been working toward better and wider utilization of wireless technology for more efficient health care for several years, and continue to develop important resources and standards. There is still much to be done to better understand how the dynamic worlds of wireless technology and medical devices can be safely and effectively converged. The future holds much promise for continued progress for both these worlds. The challenge will be to communicate and coordinate. Many opportunities are available to develop tools, resources and products to innovate and improve wireless medical device systems. The concept of wireless test beds as applicable to medical device systems could represent a potential resource to help spur communication, coordination, and innovation. While the path forward is still unclear the potential to aid innovators, designers, manufacturers, and users holds great promise.

Further information about wireless medical devices can be found at the FDA, CDRH medical device web site:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ConnectedHealth/WirelessMedicalDevices/default.htm>